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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
WIEST, PHILIP R	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
05/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

HH

Office Action Summary	Application No.	Applicant(s)	
	10/791,869	JANSEN ET AL.	
	Examiner	Art Unit	
	Phil Wiest	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 February 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. In the response filed 2/5/07, applicant amended Claims 12, 15, and 22, and added new claims 24-33. Claims 12-33 are currently pending.

Claim Rejections - 35 USC § 112

2. Claims 30-33 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not teach a free edge extending with a diameter greater than the rest of the edge portion away from the inward projection, nor does it teach the benefits of such an arrangement.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 12-19, 21-23, and 26-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Thiebault et al. (US 2002/0121496).

5. With respect to claim 12, Thiebault et al. discloses a fluid transfer set comprising a lid portion (44) and an edge portion (50) forming a receiving cap (20). Thiebault further discloses a piercing mandrel (92) that includes a sealing portion and a piercing portion (84), which is configured to pierce the elastic stopper. The piercing mandrel is *fully capable* of piercing the elastic stopper while bead is being disposed in the space if the operator presses the piercing mandrel downward at the same time. The piercing mandrel also comprises a flow channel configured to convey fluid away from the container. Thiebault further discloses an elastic stopper (36) whose edge portion is configured to center the bead within the space, and a sealing portion (52, 82 and 86) with a greater diameter than that of the piercing portion (84). The sealing portion is configured to contact the elastic stopper when the bead is substantially disposed in the space. The transfer device further comprises a central longitudinal axis, as per clam 13, as shown in Figures 3-5.

6. With respect to claims 14 and 15, Thiebault et al. discloses that the piercing mandrel has a stepped diameter (84) as it transitions from the front piercing portion to the sealing portion. The sealing portion of the device includes an end face (86), and the interface (52) between the end face and the elastic stopper (36) has a substantially annular shape.

7. With respect to claims 16 and 17, Thiebault et al. discloses that when a beaded bottle (22) is substantially disposed in the space, the piercing mandrel (84) is configured

to pierce the elastic stopper (36), as per claim 16. In addition, the edge portion of the transfer device (50) includes an inward projection (46a) capable of engaging the behind portion of the bead (26), as per claim 17.

8. As interpreted by the examiner with respect to claim 18, Thiebault et al. discloses a fluid transfer device in which the outer wall of the sealing portion (52) is of a different diameter than the outer wall of the bead-receiving portion (46).

9. With respect to claim 19, the transfer set as disclosed by Thiebault et al. also includes an integrated sealing element, formed by elements 52, 82, and 86. These elements restrict flow to all locations except for the piercing mandrel.

10. With respect to claim 21, Thiebault et al. discloses a piercing mandrel in which the piercing portion (18) is substantially conically shaped.

11. Regarding claims 22 and 23, Thiebault et al. discloses a sealing portion that covers the piercing mandrel (82) in a conical fashion, as per claim 22. The transition between the sealing portion and the mandrel is substantially stepless, as per claim 23.

12. With respect to Claim 26, the inward projection 46a is disposed radially around the piercing mandrel even before the piercing portion pierces the elastic stopper.

13. With respect to Claim 27, the piercing portion 84 of the piercing mandrel is disposed closer to the inward projection 46a than to the lid portion 44. See Figure 1.

14. With respect to Claims 28 and 29, the sealing portion 82 of the piercing mandrel is configured such that it is *fully capable* of piercing the elastic stopper while the bead engages the inward projection if the operator presses the piercing mandrel downward at the same time.

15. Claims 12, 13, 15, 19, 22, 24, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Wadsworth, Jr. (US 5, 374, 264).

16. With respect to Claims 12 and 13, Wadsworth Jr. discloses a fluid transfer device comprising a lid portion 40 and an edge portion 15 forming a receiving cap, the receiving cap defining a space configured to receive a bead of a container closed by an elastic stopper, the edge portion being configured to center the bead of a container (via angled walls 13 and ribs 32) within the space when the bead is substantially disposed within the space, and a piercing mandrel 26 connected to the lid portion and projecting into the space. The piercing mandrel 26 includes a piercing portion 23 configured to pierce the elastic stopper while the bead is being disposed in the space. The mandrel further comprises a sealing portion 24 having a diameter greater than the mandrel, the sealing portion being configured to contact the elastic stopper when the bead is substantially disposed in the space (see figure 4), and a flow channel being configured to convey fluid away from the container. The receiving cap is symmetrical about a central longitudinal axis 34, as per Claim 13

17. With respect to Claims 15 and 19, the sealing portion 24 of the mandrel includes an end face (adjacent lid portion 40) that is substantially annular. The annular end face of the sealing portion is connected to the rest of the sealing element, and effectively prevents fluid from flowing around the sides of the mandrel (see Figure 2), as per Claim 19.

18. With respect to Claim 22, the sealing portion 24 is substantially conically shaped and adjoins the piercing portion of the mandrel.

19. With respect to Claims 24 and 25, the piercing mandrel is embedded in and stationary relative to the lid portion

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

21. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

22. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thiebault et al. in view of Meyer (US 5,358,501).

Thiebault et al. teaches all the limitations of the parent claims 12, 15, and 19, but does not teach that the sealing element is an o-ring. Thiebault et al. discloses a round opening between the edge portion and the sealing portion, thus motivating one skilled in the art to include a seal that fits round openings.

The use of o-rings for sealing means in medical devices is known in the art. Meyer (5358501) discloses a storage bottle containing a constituent of a medical solution, which employs an o-ring as a sealing element between the two containers. Thus, it would be obvious to one skilled in the art to apply the o-ring of Meyer to the fluid transfer device of Thiebault et al., because doing so will achieve an effective and inexpensive sealing means, thereby preventing the loss of fluid around the edges of the vial.

23. Claims 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thiebault et al. in view of Zinger et al. (US 6,238,372). Thiebault et al. discloses the device of Claims 12 and 17, but does not disclose that the edge portion further

comprises a free edge extending away from the inward projection 46a. Zinger et al. discloses a fluid transfer device comprising an edge portion that has an inward projection that holds the bead of a container in position and a free edge portion extending away from the inward projection (see Figure 3). The free edge portion has a larger inner and outer diameter than the rest of the receiving cap 20" and therefore is capable of guiding a container such that it is centered as it is inserted onto the piercing mandrel. It is very important that the mandrel pierces the elastic stopper in the center in order to reduce the chances of the stopper tearing as well as ensure that the neck of the boddle does not impede the mandrel. Furthermore, the use of flanges such as these is well established in the art in order to properly center a mandrel over the stopper of a bottle. Therefore, it would have been obvious to one skilled in the art at the time of invention to modify the fluid transfer device of Thiebault et al. with the outwardly-extending flares of Zinger et al. in order to guide a bottle into the desires position as it is inserted.

Response to Arguments

24. Applicant's arguments filed 2/5/07 have been fully considered but they are not persuasive. Because the act of lowering the piercing mandrel into the internal space of the receiving cap is a manual action, the transfer set of Thiebault et al. is fully capable of being used in such a way that the mandrel pierces the stopper at the same time the bead of a bottle is inserted into the internal space.

Regarding applicant's argument regarding claim 20, the use of o-rings is a common and obvious choice for sealing cylindrical openings in a fluid handling system.

Conclusion

25. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571) 272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PRW
5/11/07

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER